k100917

NOV 3 2010

Premarket Notification
510(k) Summary
FIDIS™ VASCULITIS Assay kit

Assigned 510(k) Number: k100917

1) Submitted by :

Name:	Biomedical Diagnostics S.A (bmd)
Contact Person:	Christelle COURIVAUD Regulatory Affairs Manager
Address:	Actipole 25, 4-6 Bld de Beaubourg 77435 Marne-La-Vallée Cedex 2 FRANCE
Telephone:	33 (0)1 64 62 10 12
Fax:	33 (0)1 64 62 09 66
Establishment Registration Number:	3003935253

US Agent correspondent:
P. Ann Hoppe, President
Hoppe Regulatory Consultants LLC
103 South Cherry Street
Falls Church VA 22046
703 532 1145 Office
404 441 0152 Mobile
+3725 311 0011 Europe/Africa
e-fax: 703 592 9024
E-mail: HoppeRegulatory@cs.com

2) Device Name

Trade/Proprietary Name :	**FIDIS™ VASCULITIS Assay kit**
Classification Names:	Test system, Antineutrophil Cytoplasmic Antibodies (ANCA) Devices, Measure, Antibodies to Glomerular Basement Membrane (GBM)
Common/Usual Name :	**MX007 – MX507 - FIDIS™ VASCULITIS**: Detection test for autoantibodies directed against Myeloperoxidase (MPO), Serine Proteinase 3 (PR3) and Glomerular Basement Membrane (GBM) in human serum

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Trade/Proprietary Name : **FIDIS™ Analyzer**

Classification Name: Instrumentation for Chemical Multiplex Systems

Trade/Proprietary Name : **CARIS™ System**

Classification Name: Device, Microtiter diluting/Dispensing

3) Legally marketed equivalent device

510K Number	Device Classification Name	Manufacturer Name
K070458	**FIDIS™ VASCULITIS**	Biomedical Diagnostics S.A.(bmd)

4) Device description

FIDIS™ VASCULITIS* kit is a multiplex flow immunoassay, which allows simultaneous identification and detection of several antibodies.

FIDIS™ VASCULITIS* is based on the use of distinct uniform size color-coded microsphere sets and a benchtop flow cytometer interfaced to digital signal processing hardware and software. A red diode laser beam in the flow cytometer recognizes each set of microspheres on the basis of its unique fluorescence intensity (red and infrared) thus identifying which parameter is being tested. At the same time, a green laser beam illuminates the external second molecule fluorescence to quantify the reaction related to the specific antigen.

Three different fluorescently "colored" sets of microspheres are coated with antigens associated with various primary systemic small blood vessel vasculitides and glomerular basement membrane disease (MPO, PR3 and GBM). An additional microsphere (Internal Bead standard) set is coated with anti-IgG to ensure that false negative results due to operational error are detected.
The four different sets of microspheres are mixed together. The mixture is lyophilized and constitutes the final microspheres reagent.

The test is performed using a 96 wells microplate with a filtering membrane at the bottom of the wells.

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⇨ In the first step, the sample is distributed in each well containing the reconstituted microspheres mixture, allowing any anti-MPO, anti-PR3 or anti-GBM antibodies present to bind to the immobilized antigens on the microspheres, as well as free IgG to bind to the anti-IgG microsphere.
⇨ After incubation, a wash step using a filtration process removes the unbound antibodies.
⇨ A phycoerythrin anti-human IgG conjugate is then added that binds to the previously bound antibodies.
⇨ A final wash step stops the reaction and eliminates the unbound conjugate.
⇨ The reaction is then measured directly by the flow cytometer, which distinguishes each set of microspheres by its fluorescence color while simultaneously measuring the average fluorescence emitted by the conjugate.
⇨ A calibration system allows the determination of the titer (AU/mL) of each sample by interpolation for each antigenic specificity.

Kit components

	MX007	MX507
96 wells microplate with filtering membrane and lid. **MP**	1 plate	5 plates
Vial **(A)** of color-coded microsphere set of 3 sensitized by MPO (purified from human blood), PR3 (purified from human leucocytes) and GBM (purified from bovine tissues). Lyophilized (to be reconstituted with the buffer named D) **MICROSPHERES**	qs 6mL	5 x qs 6mL
Vial **(B1)** of sample dilution buffer (white vial) Ready to use **DIL SPE**	2 x 115mL	10 x 115mL
Vial of calibrator titered in arbitrary units for the specificities to be measured. Ready to use ***Each titer is printed on the vial label*** **CAL**	1 x 1.5mL	5 x 1.5mL
Vial of positive control concentrate. This control has a standard reactivity, which provides evidence of the proper reagents activity and proper assay performance. To be diluted ***Expected values are printed on the vial label.*** **CONTROL +**	1 x 250µL	5 x 250µL
Vial of negative control concentrate To be diluted **CONTROL -**	1 x 250µL	5 x 250µL
Vial of anti-human IgG coupled to phycoerythrin Ready to use **CONJ IgG**	1 x 12mL	5 x 12mL
Vial **(C1)** of washing buffer (black vial) Ready to use **BUF WASH**	1 x 100mL	5 x 100mL
Vial **(D)** of reconstitution buffer for the microsphere set Ready to use **BUF MICROSPHERES**	1 x 6mL	5 x 6mL

S.A au Capital de 2 755.46 Euros
RCS Meaux: B 339 685 612
Siret: 339 685 612 00048-APE: 514N
N° TVA Intracommunautaire: FR 68 339 685 612

Registered Office :
Actipole 25
4-6 bd de Beaubourg
77435 Marne La Vallée cedex 2

Tel: 33 (0)1 64 62 10 12
Fax : 33 (0)1 64 62 09 66
Email: bmd@bmd-net.com
Internet : www.bmd-net.com

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5) Intended use

FIDIS™ VASCULITIS Assay kit

The **FIDIS™ VASCULITIS*** kit is a semi-quantitative homogeneous fluorescent-based microparticle immunoassay using flow cytometry. The test system is used to simultaneously detect the presence of anti-neutrophil cytoplasmic antibodies (ANCA) directed against Myeloperoxidase (*MPO*), Serine Proteinase 3 (*PR3*) and antibodies directed against glomerular basement membrane (GBM) in human serum samples.

The results of the **FIDIS™ VASCULITIS*** test are to be used in conjunction with the clinical findings and the other laboratory tests to aid in the diagnosis of various primary systemic small blood vessel vasculitides and glomerular basement membrane disease.

Clinical utility:

The detection of ANCA is associated with primary systemic small blood vessel vasculitides: Wegener's granulomatosis, Churg Strauss syndromes, microscopic periarteritis and idiopathic crescentic glomerulonephritis; and the detection of anti-GBM antibodies is associated with Goodpasture's syndrome.

FIDIS™ VASCULITIS* kit uses serum only, and is to be run on the FIDIS™ Instrument and MLX-BOOSTER Software.

FIDIS™ VASCULITIS* kit may be used with the **CARIS™ system** (diluting and dispensing device).

This kit is for *In vitro* diagnostic use.

* Detection of the serologic markers for primary systemic small blood vessel vasculitides (ANCA) and for Goodpasture syndrome (GBM).

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6) Technological characteristics

The following table summarizes similarities and differences between the modified **FIDIS™ VASCULITIS and the predicate device FIDIS™ VASCULITIS (K070458).**

Comparison with the predicate

		Predicate Device FIDIS™ VASCULITIS K070458	Modified Device FIDIS™ VASCULITIS
Intended use		Individual determination in human serum, of IgG antibodies against: MPO, PR3 and GBM	Same
Antigen		- MPO: purified antigen - PR3: purified antigen - GBM: purified antigen	Same
CUT-OFF	**Negative**	<20 AU/mL for the 3 specificities	Same
	Equivocal	20-25 AU/mL for the 3 specificities	Same
	Positive	>25 AU/mL for the 3 specificities	Same
Beads		Vial of color-coded microsphere set ready to use (6mL)	Vial of color-coded microsphere set Lyophilized (Quantity sufficient to obtain 6mL after reconstitution)
Reconstitution buffer for the microsphere set		No	Vial (D) of reconstitution buffer for the microsphere set Ready to use (6mL)
Sample dilution		Sample dilution buffer – (PBS-Tween) ready to use	Same
Wash buffer		Washing buffer – (PBS-Tween) ready to use	Same
Internal standard beads		Yes	Same
Assay configuration		1 "reagent-blank" well 1 "negative control" well 1 "positive control" well 2 "calibrator" wells	Same
		Diluted sample wells	Same
Incubation time		2 x 30min. RT	Same
Assay protocol		Final wash step	Same
Software		MLX-Booster Version 2.2	Same
Assay technology		Flow cytometric	Same
Number of reading microspheres per parameter		200	100
Reading time		60 seconds	90 seconds
Microplate sealing films		6	No
Sample delivery		Manual pipetting	Same
Automated sample delivery (option)		CARIS™ (pipettor)	Same

7) Performance Characteristics

7.1. Precision study – Using Manual Pipetting

Precision of the assay was assessed using 6 samples for each of the three parameters (MPO, PR3, GBM). Precision was determined by calculating the within-run (intra-assay) and the between-run (inter-assay).

- For within-run: 10 tests in a same run.
- For between-run: 5 runs, 3 tests per run

Table 1: Summary of FIDIS™ VASCULITIS precision results using Manual Pipetting

Sample range	MPO, PR3 and GBM parameters			
	Within-run		Between-run	
	Minimal %CV	Maximal %CV	Minimal %CV	Maximal %CV
≤ 25 AU/mL	3%	6%	4%	11%
26 to 400 AU/mL	2%	9%	2%	12%

7.2. Comparison study with predicate – Using Manual Pipetting

bmd has compared the results obtained with **modified FIDIS™ VASCULITIS** versus the results obtained with **predicate FIDIS™ VASCULITIS K070458.**

The study was performed on 280 samples characterized with the predicate test and the result repartition is described below:

- **197 samples were positive** for one or more parameters ANCA and/or GBM. Of the 197 samples: 192 are positive for one parameter, 3 are positive for two parameters and 2 are positive for all three parameters.
- **83 negative samples.**

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a. First set of measures based on included the equivocal results with the test negative results.

Table 2a: MPO performances

MPO		PREDICATE FIDIS™ VASCULITIS K070458		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS	Positive	95	1	96
	Negative	0	184	184
	Total	95	185	280

There were 15 equivocal results with the assay. For purposes of calculation, these results were considered to be negative.

- **Positive percent agreement: 100% (95/95)**
- **Negative percent agreement: 99.4% (184/185)**
- **Overall agreement: 99.6% (279/280)**

Table 3a: PR3 performances

PR3		PREDICATE FIDIS™ VASCULITIS K070458		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS	Positive	89	0	89
	Negative	1	190	191
	Total	90	190	280

There were 3 equivocal result with the assay. For purposes of calculation, these results were considered to be negative.

- **Positive percent agreement: 98.9% (89/90)**
- **Negative percent agreement: 100% (190/190)**
- **Overall agreement: 99.6% (279/280)**

Table 4a: GBM performances

GBM		PREDICATE FIDIS™ VASCULITIS K070458		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS	Positive	18	0	18
	Negative	0	262	262
	Total	18	262	280

There were 0 equivocal results with the assay.

- **Positive percent agreement: 100% (18/18)**
- **Negative percent agreement: 100% (262/262)**
- **Overall agreement: 100% (280/280)**

b. Second set of measures based on included the equivocal results with the test positive results.

⇨ MPO results

Table 2b: MPO performance

MPO		PREDICATE FIDIS™ VASCULITIS K070458		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS	Positive	103	2	105
	Negative	5	170	175
	Total	108	172	280

There were 15 equivocal results with the assay. For purposes of calculation, these results were considered to be positive.

- **Positive percent agreement: 95.4% (103/108)**
- **Negative percent agreement: 98.8% (170/172)**
- **Overall agreement: 97.5% (273/280)**

⇨ PR3 results

Table 3b: PR3 performance

PR3		PREDICATE FIDIS™ VASCULITIS K070458		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS	Positive	90	2	92
	Negative	0	188	188
	Total	90	190	280

There were 3 equivocal results with the assay. For purposes of calculation, these results were considered to be positive.

- **Positive percent agreement: 100% (90/90)**
- **Negative percent agreement: 98.9% (188/190)**
- **Overall agreement: 99.3% (278/280)**

⇨ GBM results

Table 4b: GBM performance

GBM		PREDICATE FIDIS™ VASCULITIS K070458		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS	Positive	18	0	18
	Negative	0	262	262
	Total	18	262	280

There were 0 equivocal results with the assay.

- **Positive percent agreement: 100% (18/18)**
- **Negative percent agreement: 100% (262/262)**
- **Overall agreement: 100% (280/280)**

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Table 5: Summary of performance agreement results

Antigenic Specificity		MPO	PR3	GBM
Sample number		280	280	280
Positive percent agreement	equivocal results included with the test negative results	100%	98.9%	100%
	equivocal results included with the test positive results	95.4%	100%	100%
Negative percent agreement	equivocal results included with the test negative results	99.4%	100%	100%
	equivocal results included with the test positive results	98.8%	98.9%	100%
Overall agreement	equivocal results included with the test negative results	99.6%	99.6%	100%
	equivocal results included with the test positive results	97.5%	99.3%	100%
95%CI (EP12-A Chap 9.2.2.)	equivocal results included with the test negative results	93-100%	94-100%	N/A
	equivocal results included with the test positive results	91-100%	93-100%	N/A
95%CI For positive agreement (EP12-A Chap 9.1.1.)	equivocal results included with the test negative results	N/A	N/A	82-100%
	equivocal results included with the test positive results	N/A	N/A	82-100%
95%CI For negative agreement (EP12-A Chap 9.1.1.)	equivocal results included with the test negative results	N/A	N/A	99-100%
	equivocal results included with the test positive results	N/A	N/A	99-100%

All of results show that **FIDIS™ VASCULITIS system** can be considered substantially equivalent to the predicate **K070458 FIDIS™ VASCULITIS system.**

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7.3.Performance data for modified FIDIS™ VASCULITIS with CARIS™ (diluting/ dispensing Device)

a. Precision study

Internal study was conducted to evaluate the reproducibility of the use of **CARIS™** with **modified FIDIS™ VASCULITIS.**

Precision of the assay was assessed using 6 samples for each of the three parameters (MPO, PR3, GBM). Precision was determined by calculating the within-run (intra-assay) and the between-run (inter-assay).

- For within-run: 10 tests in a same run.
- For between-run: 5 runs, 3 tests per run.

Table 6: Summary of CARIS™ precision results

Sample range	MPO, PR3 and GBM parameters			
	Within-run		Between-run	
	Minimal %CV	Maximal %CV	Minimal %CV	Maximal %CV
≤ 25 AU/mL	5%	8%	4%	16%
26 to 400 AU/mL	5%	12%	2%	12%

b. Comparison studies (manual versus automated assay preparation steps)

bmd has compared the results obtained with **modified FIDIS™ VASCULITIS** for **manual or automated (with CARIS™).**assay preparation steps.

The study was performed on 106 samples characterized with the **modified FIDIS™ VASCULITIS** with **manual** assay preparation step.

The result repartition is described below:

- 98 **positive samples** for one or more parameters ANCA and/or GBM. Of the 91 samples, 94 are positive for one parameter, 2 are positive for two parameters and 2 are positive for all three parameters.
- 8 **negative samples**

a. First set of measures based on included the equivocal results with the test negative results.

⇨ **Table 7a: MPO performances**

MPO		MODIFIED FIDIS™ VASCULITIS Manual		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS With CARIS™	Positive	40	0	40
	Negative	2	64	66
	Total	42	64	106

There were 2 equivocal results with the assay. For purposes of calculation, these results were considered to be negative.

- **Positive percent agreement: 95.2% (40/42)**
- **Negative percent agreement: 100% (64/64)**
- **Overall agreement: 98.1% (104/106)**

⇨ **Table 8a: PR3 performances**

PR3		MODIFIED FIDIS™ VASCULITIS Manual		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS With CARIS™	Positive	40	2	42
	Negative	1	63	64
	Total	41	65	106

There were 4 equivocal results with the assay. For purposes of calculation, these results were considered to be negative.

- **Positive percent agreement: 97.6% (40/41)**
- **Negative percent agreement: 96.9% (63/65)**
- **Overall agreement: 97.2% (103/106)**

⇨ **Table 9a: GBM performances**

GBM		MODIFIED FIDIS™ VASCULITIS Manual		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS With CARIS™	Positive	24	0	24
	Negative	0	82	82
	Total	24	82	106

There were 0 equivocal results with the assay.

- **Positive percent agreement: 100% (24/24)**
- **Negative percent agreement: 100% (82/82)**
- **Overall agreement: 100% (106/106)**

b. Second set of measures based on included the equivocal results with the test positive results.

⇨ MPO results

Table 7b: MPO performance

MPO		MODIFIED FIDIS™ VASCULITIS Manual		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS With CARIS™	Positive	42	0	42
	Negative	0	64	64
	Total	42	64	106

There were 2 equivocal results with the assay. For purposes of calculation, these results were considered to be positive.

- **Positive percent agreement: 100% (42/42)**
- **Negative percent agreement: 100% (64/64)**
- **Overall agreement: 106% (106/106)**

⇨ PR3 results

Table 8b: PR3 performance

PR3		MODIFIED FIDIS™ VASCULITIS Manual		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS With CARIS™	Positive	44	0	44
	Negative	0	62	62
	Total	44	62	106

There were 4 equivocal results with the assay. For purposes of calculation, these results were considered to be positive.

- **Positive percent agreement: 100% (44/44)**
- **Negative percent agreement: 100% (62/62)**
- **Overall agreement: 100% (106/106)**

⇨ GBM results

Table 9b: GBM performance

GBM		MODIFIED FIDIS™ VASCULITIS Manual		
		Positive	Negative	Total
MODIFIED FIDIS™ VASCULITIS With CARIS™	Positive	24	0	24
	Negative	0	82	82
	Total	24	82	106

There were 0 equivocal results with the assay.

- **Positive percent agreement: 100% (24/24)**
- **Negative percent agreement: 100% (82/82)**
- **Overall agreement: 100% (106/106)**

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Table 10: Summary of performance agreements results obtained with CARIS™ versus manual

Antigenic Specificity		MPO	PR3	GBM
Sample number		106	106	106
Positive percent agreement	equivocal results included with the test negative results	95.2%	97.6%	100%
	equivocal results included with the test positive results	100%	100%	100%
Negative percent agreement	equivocal results included with the test negative results	100%	96.9%	100%
	equivocal results included with the test positive results	100%	100%	100%
Overall agreement	equivocal results included with the test negative results	98.1%	97.2%	100%
	equivocal results included with the test positive results	100%	100%	100%
95%CI (EP12-A Chap 9.2.2.)	equivocal results included with the test negative results	87-100%	86-100%	N/A
	equivocal results included with the test positive results	N/A	N/A	N/A
95%CI For positive agreement (EP12-A Chap 9.1.1.)	equivocal results included with the test negative results	N/A	N/A	86-100%
	equivocal results included with the test positive results	92-100%	92-100%	86-100%
95%CI For negative agreement (EP12-A Chap 9.1.1.)	equivocal results included with the test negative results	N/A	N/A	99-100%
	equivocal results included with the test positive results	94-100%	94-100%	96-100%

All of previous evaluations results indicate that manual and automated **(with CARIS™)** assay preparation steps are substantially equivalent.

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8) Conclusions

=> In conclusion, all supporting data demonstrate that the **FIDIS™ VASCULITIS system** can be considered substantially equivalent to the predicate device.
=> All comparative studies indicate that manual and automated **(with CARIS™)** assays provide results that are statistically comparable.

S.A au Capital de 2 755.46 Euros
RCS Meaux: B 339 685 612
Siret: 339 685 612 00048-APE: 514N
N° TVA Intracommunautaire: FR 68 339 685 612

Registered Office :
Actipole 25
4-6 bd de Beaubourg
77435 Marne La Vallée cedex 2

Tel: 33 (0)1 64 62 10 12
Fax : 33 (0)1 64 62 09 66
Email: bmd@bmd-net.com
Internet : www.bmd-net.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Biomedical Diagnostics (bmd) SA
c/o Ms. Christelle Courivaud
Regulatory Manager
Actipole 25, 4-6 Bld de Beaubourg
77435 Marne-La-Vallee Cedex 2
France

NOV 0 3 2010

Re: k100917
Trade/Device Name: FIDIS™ VASCULITIS Assay Kit
Regulation Number: 21CFR§866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MOB, MVJ
Dated: October 6, 2010
Received: October 7, 2010

Dear Ms. Courivaud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

NOV 0 3 2010

510(k) Number (if known): k100917

Device Name: **FIDIS™ VASCULITIS**

Indication For Use:

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The results of the **FIDIS™ VASCULITIS*** test are to be used in conjunction with the clinical findings and the other laboratory tests to aid in the diagnosis of various primary systemic small blood vessel vasculitides and glomerular basement membrane disease.

Clinical utility:

The detection of ANCA is associated with primary systemic small blood vessel vasculitides: Wegener's granulomatosis, Churg Strauss syndromes, microscopic periarteritis and idiopathic crescentic glomerulonephritis; and the detection of anti-GBM antibodies is associated with Goodpasture's syndrome.

FIDIS™ VASCULITIS* kit uses serum only, and is to be run on the FIDIS™ Instrument and MLX-BOOSTER Software.

FIDIS™ VASCULITIS* kit may be used with the **CARIS™ system** (diluting and dispensing device).

This kit is for *In vitro* Diagnostic Use.

* Detection of the serologic markers for primary systemic small blood vessel vasculitides (ANCA) and for Goodpasture syndrome (GBM).

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety